

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE CARRIERS' POLICIES FOR
TRANSCRANIAL DOPPLERS:
A NEW TECHNOLOGY**



MARCH 1993 OEI-03-91-00951

EXECUTIVE SUMMARY

PURPOSE

This report reviews Medicare carriers' coverage policies for transcranial dopplers, a new technology.

BACKGROUND

Transcranial doppler (TCD) is a noninvasive ultrasound technique that measures blood flow velocities in the major arteries in the skull. The TCD technology was introduced in 1982.

The Health Care Financing Administration (HCFA) contracts with private insurance organizations, called carriers, to make Medicare coverage determinations and disburse payments. When HCFA issues policy guidance on a new technology, carriers are required to follow it. When no guidance is provided, each carrier establishes its own coverage policies.

Carriers use the HCFA Common Procedure Coding System (HCPCS) to reimburse Medicare Part B services, including physician services. The HCPCS is based on the Current Procedural Terminology (CPT) coding system, which was developed by the American Medical Association (AMA) in 1966 and updated annually. Effective January 1, 1992, two new CPT codes were established for TCD services. Physicians use the new codes to claim Medicare reimbursement for TCD tests performed on or after that date.

In a related study ("Medicare Carrier Assessment of New Technologies," OEI-01-88-00010), we found inconsistencies in carrier coverage and pricing decisions and a significant need for HCFA guidance involving new technologies. We recommended HCFA improve its ability to identify emerging technologies and make more consistent coverage decisions for new technologies.

METHODOLOGY

In late 1991, we reviewed carriers' coverage policies and guidelines for TCDs. In early 1992, we recontacted those carriers that did not cover TCDs in 1991 to determine if they had changed their policies, and, if so, what had influenced their decisions. We also obtained payment information for the two TCD procedure codes for the first quarter of 1992 from the Part B Extract Summary System (BESS) file. We obtained technical and clinical information on TCDs from medical literature, professional provider organizations, and individual physician experts.

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INTRODUCTION

PURPOSE

This report reviews Medicare carriers' coverage policies for transcranial dopplers, a new technology.

BACKGROUND

Transcranial doppler (TCD) is a noninvasive ultrasound technique which measures circulation in the major arteries inside the skull. First introduced in 1982, the TCD is used to determine changes in blood flow velocity. Increased velocity generally indicates a narrowed blood vessel.

The test is done with a hand-held instrument which transmits ultrasonic energy from a probe to a point inside an artery in the brain. Some of the energy is reflected back to the probe. It is then analyzed, displayed on a monitor, and recorded graphically.

According to the American Academy of Neurology's *Report of the Therapeutics and Technology Assessment Committee*, TCD has a number of established and investigational uses. Their March 1990 report lists five conditions for which TCD is of established value, including detecting severe stenosis in the intracranial arteries. See Appendix A for a complete list of uses.

The Health Care Financing Administration (HCFA) contracts with private insurance organizations, called carriers, to make Medicare coverage determinations and disburse payments in a local service area. When HCFA issues policy guidance on a new technology, carriers are required to follow it. When such guidance is not offered, each carrier makes its own coverage determinations. Claims for new or unusual devices, tests, procedures, or treatment modalities can present serious coverage issues.

Carriers use the HCFA Common Procedure Coding System (HCPCS) to reimburse for Medicare Part B services, which includes physician and outpatient services. The HCPCS is based on a coding system maintained in the *Physicians' Current Procedural Terminology (CPT) Manual*. The American Medical Association (AMA) developed CPT codes in 1966 and publishes annual updates.

Effective January 1, 1992, the AMA established two new codes to represent TCD services. Physicians and other providers of services use the new codes to claim Medicare reimbursement for TCD tests performed on or after that date. First quarter 1992 allowances nationally for the two codes approached \$580,000.

The Medicare Carriers Medical Directors New Technology Workgroup and HCFA's Coverage and Payment Technical Advisory Group are two entities which evaluate new technologies for the Medicare program. Composed of medical directors from six

carriers, the New Technology Workgroup meets periodically to research new technologies and make recommendations to HCFA as well as other carriers. The HCFA's Coverage and Payment Technical Advisory Group consists of 10 carrier medical directors who recommend policy decisions on various issues, including new technologies, to HCFA's Bureau of Policy Development.

In a related study ("Medicare Carrier Assessment of New Technologies," OEI-01-88-00010), we found (1) a significant need for HCFA guidance to carriers on new technologies, and (2) carrier inconsistencies in coverage and pricing decisions involving new technologies. We recommended that HCFA improve its own capability and that of the carriers to identify emerging technologies and to make more informed, explicit, and consistent coverage decisions concerning new technologies.

In its comments on the earlier report, HCFA recognized that problems exist with carriers' assessment of new technologies and noted that it had taken several initiatives to improve technology assessment. The HCFA was concerned that our findings, at least in part, were no longer valid because of its efforts. It asked the Office of Inspector General to conduct another study to assess the effectiveness of its initiatives. We plan to conduct such a study in the future. The current report sheds light on the larger picture by providing a case study of how coverage and payment policies are made for new technologies.

METHODOLOGY

In late 1991, we contacted 36 Medicare carriers representing 58 geographical jurisdictions to obtain their coverage guidelines and policies for TCDs. (Some carriers service more than one jurisdiction.) Responses were received from carriers representing 56 jurisdictions. In this report, we refer to the jurisdictions as carriers.

During the first quarter of 1992, we recontacted the carriers that did not cover TCDs in 1991 to determine if they had changed their policies. If the carriers had changed their coverage policies, we asked what influenced their decisions. We also obtained payment information for the two TCD procedure codes for the first quarter of 1992 from the Part B Extract Summary System (BESS) file.

We obtained technical and clinical information from medical literature, physician experts, and professional organizations, including the Medicare Carriers Medical Directors New Technology Workgroup, HCFA's Coverage and Payment Technical Advisory Group, the American Academy of Neurology, the American Society of Neuroimaging, the Intersocietal Commission for Accreditation of Vascular Laboratories, and the American Institute of Ultrasound in Medicine.

Our review was conducted in accordance with the *Interim Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Carriers' coverage policies for transcranial dopplers are inconsistent.

Carriers' coverage decisions are not uniform, despite the fact that some carriers have provided for payment since 1988. Currently, 40 of 56 carriers cover TCD tests. Several carriers not covering TCD tests consider their use investigational.

The 40 carriers which cover TCDs differ on the conditions required for payment. Half (19 of 40) have no specific coverage criteria. Essentially, payment is made for any TCD claim submitted. The 19 carriers with no specific guidelines allowed \$188,200 while the 21 carriers with specific coverage criteria allowed \$157,278.

Twenty-one of 40 carriers covering TCDs make payment decisions based on certain conditions or criteria. Fifteen (of 21) carriers base their criteria on the American Academy of Neurology (AAN) position paper, which identifies 5 conditions for which TCDs have established value (see Appendix A). The remaining six carriers make determinations on an individual basis.

This lack of consistency among the carriers exists even though TCD technology has been on the market for several years. At least two carriers have covered TCDs since 1988, and four others began coverage in 1989. Five of the six carriers still have no specific criteria. In fact, nearly half of the 25 carriers that covered TCDs as of 1991 did not have any specific criteria for coverage. This inconsistency corroborates our previous study in which one-third of the carriers stated that, as a group, they are minimally consistent in making coverage decisions about new technologies.

As we stated in our earlier report entitled "Medicare Carrier Assessment of New Technologies":

Since each of the carriers interprets the meaning of demonstrated value and general use within its service area, coverage decisions can and do vary, reflecting differences in local practice patterns. These variations are of concern to some carrier representatives who feel that health care has become "a much more uniform process nationally than it was in 1965 when Medicare was enacted." One of the medical directors observes, "the idea of local practice patterns that was accurate 20 to 30 years ago no longer applies today." The carriers are looking for more coordination --some even say uniformity--in coverage decisions.

Some carriers pay for transcranial dopplers despite noncoverage policies.

Although 16 carriers advised us that they do not cover TCD tests, BESS statistics for the first quarter of 1992 disclosed a total of more than \$200,000 in allowances for 10 of the 16 carriers. Total carrier allowances ranged from \$254 (Nevada) to \$100,000

(Washington). We contacted these carriers during the first quarter of 1992, with all of the contacts occurring in late February or later. At that time, carrier representatives informed us that their policies prohibited payment for TCDs. Since the BESS data was unavailable at the time we spoke to these carriers, we were unable to verify the BESS data with the carriers.

New CPT codes influenced carriers' coverage decisions for transcranial dopplers.

Prior to January 1, 1992, 31 (of 56) carriers did not cover TCDs. Half (15 of 31) reversed their noncoverage determinations on or after January 1, 1992, following the introduction of CPT codes representing TCD tests. Twelve of the 15 carriers--according to contacts with 8 medical directors and 7 personnel at a supervisory or managerial level--cited the new CPT procedure codes as an influence in changing their coverage decisions. Seven carriers based the reversals solely on the new codes.

The creation of a CPT code does not mean a procedure is automatically covered under Medicare, although it could signify a growing acceptance of the service. It is HCFA's responsibility to determine if a procedure will be covered. However, when HCFA does not make a determination, carriers establish coverage policies independently. For TCDs, carriers were clearly influenced in their coverage decisions by the creation of the new CPT codes. "Physicians increase the pressure on us to cover a service when new codes are established," one medical director said.

A few carriers also mentioned provider requests, new in-house coverage policies, relative value units¹ (even though this payment system is designed to correct reimbursement inequities rather than influence coverage policies), and the Medicare Carriers Medical Directors New Technology Workgroup as influencing their decisions to provide coverage.

Despite the fact that the Workgroup concurred with the recommended uses outlined by the AAN in December 1991, carriers mentioned the new CPT codes as the reason for changing TCD coverage decisions more often than the Workgroup. (The Workgroup's recommendations are advisory only. Carriers still have the option to grant or deny coverage.)

Prior to the creation of the new CPT codes, the 25 carriers who covered TCDs used existing codes to process claims. While codes varied by carrier, over half used CPT-4 codes 93850 and 93860 (noninvasive studies of cerebral arteries other than carotid) or code 93799 (other procedures unlisted) for claims processing. Because these codes encompassed studies other than TCDs, we were not able to identify the frequency of TCD services.

¹ The relative value unit (RVU) represents the value of a unit of physician work to deliver a specific medical service in relation to the value of other medical services. Medicare uses the RVU to calculate reimbursement.

Our previous study on new technologies revealed carrier vulnerabilities in identifying claims involving such techniques, especially when billed under existing codes. A new technology billed under an established procedure code would not be recognized as new but would be paid as submitted.

A carrier's failure to recognize a new technology can lead to problems for beneficiaries, physicians, the health care industry, and program administrators. Any Medicare payments, of course, are subject to recovery. However, if not corrected promptly, such incorrect payments create an erroneous impression that Medicare now pays for the new technology.

The HCFA efforts to update the coverage process and improve communications with carriers do not appear to have resolved problems with carriers' coverage of this technology.

Our review of TCD policies indicates HCFA's efforts to update the coverage process and improve communications with carriers do not appear to have solved the problems with carriers' assessment of this new technology. We found that carriers still have conflicting or non-existent coverage policies for TCDs even though some carriers have been paying for it since 1988.

The inconsistent coverage policies may prevent Medicare payments for appropriate tests and allow payments for inappropriate tests. According to some experts, carriers may be paying for inaccurate, unnecessary, or inappropriate TCD tests. Concerns about the accuracy of TCD tests were raised by experts, providers, and professional organizations, and supported by pertinent literature.

In response to our earlier report, HCFA mentioned several initiatives they had undertaken to improve communications with carriers. These include:

- ▶ Publishing a proposed rule in the *Federal Register* which describes the coverage process in detail and which makes explicit the criteria that are to be applied when making coverage decisions.
- ▶ Requiring carriers to submit a copy of all medical coverage policies to identify carriers with widely variant policies.
- ▶ Requiring carriers to have licensed physicians as medical directors.
- ▶ Holding annual Medical Directors' Conferences with time devoted to new technology assessments.

- ▶ Discussing both emerging technology and coverage issues with HCFA's Coverage and Payment Technical Advisory Group, which includes selected physicians from carriers and HCFA.
- ▶ Providing significant pricing guidelines to carriers on new technology.

The TCD experience suggests that these initiatives have not been successful in eliminating problems with assessment and coverage for this new technology. The proposed rule has yet to be finalized.

RECOMMENDATION

In our earlier study entitled, "Medicare Carrier Assessment of New Technologies," we identified two primary problem areas: (1) a need for HCFA to provide guidance on new technologies, and (2) inconsistent carrier policies. Our findings regarding TCD technology mirror our conclusions in the earlier study.

We therefore recommend that HCFA continue its efforts to review, coordinate, and guide carrier coverage policies of this and other new technologies.

COMMENTS

The Assistant Secretary for Planning and Evaluation concurred with the report. We received no comments from HCFA.

APPENDIX A

AMERICAN ACADEMY OF NEUROLOGY POSITION ON TCD

In March 1990, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) released a position paper delineating the established and investigational uses of TCD.

Established uses of TCD:

1. Detecting severe stenosis (greater than 65 percent) in the major basal intracranial arteries.
2. Assessing patterns and extent of collateral circulation in patients with known regions of severe stenosis or occlusion.
3. Evaluating and following patients with vasoconstriction of any cause especially after subarachnoid hemorrhage.
4. Detecting arteriovenous malformations and studying their supply arteries and flow patterns.
5. Assessing patients with suspected brain death.

Investigational uses of TCD:

1. Assessing patients with migraine.
2. Monitoring during cerebral endarterectomy, cardiopulmonary bypass and other cerebrovascular and cardiovascular interventions, and surgical procedures.
3. Evaluating patients with dilated vasculopathies such as fusiform aneurysms.
4. Assessing autoregulation, physiologic, and pharmacologic responses of cerebral arteries.
5. Evaluating children with various vasculopathies such as sickle cell disease, moya moyo, and neurofibromatosis.

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